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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/441,355	05/15/1995	MICHAEL HOUGHTON	0063.021	1825

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EXAMINER	
ZEMAN, MARY K	

ART UNIT	PAPER NUMBER
1631	43

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/441,355	Applicant(s) HOUGHTON ET AL.	
	Examiner Mary K Zeman	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover she t with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *115-153,158-166 and 168-344* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *115-153,158-166 and 168-344* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *31, 37* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 115-153, 158-166 and 168-344 are pending in this application.

The amendments of 2/19/02, 5/29/02, 6/21/02, 9/6/02 and 10/22/02 have been entered.

The IDS statements filed 2/6/02 and 6/21/02 have been entered. Initialed copies of the forms are included.

The formal drawings filed 2/19/02 will be presented to the draftsman when appropriate.

Applicant is requested to review the claims for unnecessary duplication. Applicant is also requested to provide a clean copy of all claims in one document for the examiner, as the pending claims are presently scattered through multiple amendments.

Applicant should update the status of all applications in the priority status, and any application referenced in the specification as to its current status.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 118, 119, 123-125, 129-132, 136- 138, 142- 144, 148- 150, 152, 158, 160, 161, 164, 169, 170, 171, 175-177, 181, 182 and 183-344 are rejected under the judicially created

doctrine of obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 5,350,671. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of the patent is specifically for detecting the presence of antibodies that bind HCV antigens. This test performs the same method steps and has the same inherent use of screening a blood bank, or selecting particular samples because they contain HCV-specific antibodies.

The claims of the instant application are drawn to methods of selecting human samples from a supply of samples which comprise antibodies which bind HCV epitopes. No particular detecting methods are set forth in the claim, but the specification discloses immunoassays for HCV-specific antibodies. The selection is done to select samples for various intended uses: for passive immunotherapy, for preparation of polyclonal antibodies, for production of blood-products. These are merely intended use limitations which do not further limit any of the method steps.

The immunoassay of the Patent (5,350,671) detects the presence of HCV-specific antibodies in samples from human patients, in order to identify and select those samples which react, and to identify which samples do not react. Samples which do not react would appear to be free of HCV infection. The detection assay can be done with blood, plasma or serum (claim 3), the antigen can be made recombinantly (claim 2), the antigen to which the antibody reacts can be from Figure 90 (claims 10-21) or the same ATCC deposit (claim 1) recited in the instant claims.

This immunoassay was developed for the purpose of screening a supply of blood products in order to select out HCV+ samples, and to retain HCV- samples. The screening of donated blood products for the presence of known pathogens was well known in the art at the time of the invention, as evidenced by Seto (4,707,439) who provides a screening test for detecting the presence of an infectious agent that putatively causes non-A non-B hepatitis, or AIDS. A particular property of a pathogen (RT activity) is measured in a supply of samples in order to select those that are positive for viral contamination and to retain samples which are not contaminated with the pathogen.

In addressing the issue of intended use, the CAFC has stated that the intended use language in a method claim is non-limiting when the methods utilize the same method steps.

(Brystol-Meyers Squibb. Co. vs. Ben Venue Laboratories Inc. 58 USPQ2d 1508 (CAFC 2001)) Here, the detecting step of the instant claim appears to be performed with the same methods of the cited patent. The language of the preamble does not result in a manipulative difference in the steps of the claim. Further, the claimed process is not drawn to a new use: the immunoassay of the patent is directed to the same method of selecting a sample that contains antibodies against HCV.

Claims 115-122, 126, 127, 128, 132-135, 138-141, 144-147, 151-153, 158-160, 162-166, 168, 171-174, 177-180 and 183-344 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,863,719. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of the patent is specifically for detecting the presence of HCV specific polynucleotides. This test performs the same method steps and has the same inherent use of screening a blood bank, or selecting particular samples because they contain HCV-specific polynucleotides..

The claims of the instant application are drawn to methods of selecting human samples from a supply of samples which comprise HCV specific polynucleotides, or polynucleotides that hybridize to an HCV genome under stringent conditions. No particular detecting methods are set forth in the claim, but the specification discloses methods of using sections of HCV genome, DNA from the deposit, and DNA from the figures as probes for detecting HCV-specific sequences. The selection is done to select samples for various intended uses: for the cloning of more HCV sequences, for the detection of HCV in a sample, etc. These are merely intended use limitations which do not further limit any of the method steps.

The hybridization based assay of the Patent (5,863,719) detects the presence of HCV-specific polynucleotides in samples from human patients, in order to identify and select those samples which react, and to identify which samples do not react. Samples which do not react would appear to be free of HCV infection. The detection assay can be done with blood, plasma or.

This assay was developed for the purpose of screening a supply of blood products in order to select out HCV+ samples, and to retain HCV- samples. The screening of donated blood

products for the presence of known pathogens was well known in the art at the time of the invention, as evidenced by Seto (4,707,439) who provides a screening test for detecting the presence of an infectious agent that putatively causes non-A non-B hepatitis, or AIDS. A particular property of a pathogen (RT activity) is measured in a supply of samples in order to select those that are positive for viral contamination and to retain samples which are not contaminated with the pathogen.

In addressing the issue of intended use, the CAFC has stated that the intended use language in a method claim is non-limiting when the methods utilize the same method steps. (Brystol-Meyers Squibb. Co. vs. Ben Venue Laboratories Inc. 58 USPQ2d 1508 (CAFC 2001)) Here, the detecting step of the instant claim appears to be performed with the same methods of the cited patent. The language of the preamble does not result in a manipulative difference in the steps of the claim. Further, the claimed process is not drawn to a new use: the assay of the patent is directed to the same method of selecting a sample that contains HCV sequences.

Claims 118, 119, 123-125, 129-132, 136- 138, 142- 144, 148- 150, 152, 158, 160, 161, 164, 169, 170, 171, 175-177, 181, 182 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-64 of U.S. Patent No. 5,698,390. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of the patent is specifically for detecting the presence of antibodies that bind HCV antigens. This test performs the same method steps and has the same inherent use of screening a blood bank, or selecting particular samples because they contain HCV-specific antibodies.

The claims of the instant application are drawn to methods of selecting human samples from a supply of samples which comprise antibodies which bind HCV epitopes. No particular detecting methods are set forth in the claim, but the specification discloses immunoassays for HCV-specific antibodies. The selection is done to select samples for various intended uses: for passive immunotherapy, for preparation of polyclonal antibodies, for production of blood-products. These are merely intended use limitations which do not further limit any of the method steps.

The immunoassay of the Patent (5698390) detects the presence of HCV-specific antibodies in samples from human patients, in order to identify and select those samples which react, and to identify which samples do not react. Samples which do not react would appear to be free of HCV infection. The detection assay can be done with blood, plasma or serum (claim 2), the antigen can be made recombinantly (claim 4), the antigen to which the antibody reacts can be from Figures 90, 47, 14, 66 (claims 8-11) or the same ATCC deposit (claim 12) recited in the instant claims.

This immunoassay was developed for the purpose of screening a supply of blood products in order to select out HCV+ samples, and to retain HCV- samples. The screening of donated blood products for the presence of known pathogens was well known in the art at the time of the invention, as evidenced by Seto (4,707,439) who provides a screening test for detecting the presence of an infectious agent that putatively causes non-A non-B hepatitis, or AIDS. A particular property of a pathogen (RT activity) is measured in a supply of samples in order to select those that are positive for viral contamination and to retain samples which are not contaminated with the pathogen.

In addressing the issue of intended use, the CAFC has stated that the intended use language in a method claim is non-limiting when the methods utilize the same method steps. (Brystol-Meyers Squibb. Co. vs. Ben Venue Laboratories Inc. 58 USPQ2d 1508 (CAFC 2001)) Here, the detecting step of the instant claim appears to be performed with the same methods of the cited patent. The language of the preamble does not result in a manipulative difference in the steps of the claim. Further, the claimed process is not drawn to a new use: the immunoassay of the patent is directed to the same method of selecting a sample that contains antibodies against HCV.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
12/21/02

MARY K. ZEMAN
PRIMARY EXAMINER
AU 1631